

§Appl. No. 10/076,421  
Amdt. dated April 7, 2005  
Reply to Office Action of, December 16, 2004

### **REMARKS**

#### **Rejection under 112, first paragraph**

It is stated on Page 2 of the Office action "the disclosure is clearly not enabled for the full breadth of protection directed toward any sundry 'anti-HIV' agent that is capable of binding to CD87." However, pending claims 27 and 31 recite "an amino-terminal fragment of the high molecular weight urokinase-type plasminogen activator (HMV-uPA) as an active component, the fragment being contained in a sterile aqueous or non-aqueous medium, wherein the fragment comprises amino acids 21-155 of the prepro-urokinase (sc-uPA) and does not extend beyond amino acid 178 of the sc-uPA." Thus, claim 27 is not directed toward any sundry anti-HIV agent that is capable of binding to CD878, but to a certain fragment defined by a basic protein and amino acid positions in it. This is still more evident with claims 28 and 32, which further recites a fragment with the amino acid positions 21-155. Further, the fragment recited in claims 29 and 33 are also not directed to the broad spectrum of agents as pointed out by the Examiner, but to a HMW-uPA's fragment which contains an EGF-like domain, a Kringle domain and a urokinase receptor binding domain and no portion of the B-chain. It does not appear that these claims have been considered, especially in view of the examiner's comments on Page 6 of the previous Office action, and repeated on Page 2, lines 1-4 of the this current Office action.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or the references when combined) must teach or suggest all the claim limitations. See, MPEP §2143. It is alleged in the Office action that it would have been obvious have prepared sterile solutions, but no evidence to support the motivation to make such a modification to the cited prior art has been provided. Stoppelli et al. merely purifies and

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describes the binding activity of ATF, but does not disclose any pharmacological activity relevant to treating a disease or to its use as a drug. In absence of this information, there especially would be no motivation to have formulated with the fragment with an "aqueous solution of one or more pharmaceutically acceptable inert solutes and the non-aqueous medium is selected from the group consisting of polyalcohols, vegetable oils and organic esters. Compare Claim 30. See also Claim 34.

Moreover, the Office action has failed to even address aspects of Claims 31 and 33 in which a "dry powder" is recited. As discussed above, to sustain a rejection under §103, the prior art must teach or suggest all the claim limitations." There is no mention in the cited prior art or in the Office action of the aspects recited in Claims 31 and 33.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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